### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

JON RAHN,	individually	and on	behalf o	of all
others simila	rly situated,			

No. \_\_\_\_\_

Plaintiff,

v.

GENZYME CORPORATION and HENRI A. TERMEER,

Defendants.

#### CLASS ACTION COMPLAINT AND JURY TRIAL DEMAND

- 1. This is a federal securities fraud action brought by Plaintiff Jon Rahn ("Plaintiff") on behalf of all purchasers (the "Class") of the common stock of Genzyme Corporation ("Genzyme" or the "Company") between and including June 26, 2008 and July 21, 2009 (the "Class Period"). This action is brought against Genzyme and its President and Chief Executive Officer, Henri A. Termeer ("Termeer"), (collectively, the "Defendants") for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. 1
- 2. The allegations in this Complaint are based upon information and belief, except as to allegations specifically pertaining to Plaintiff, which are based on personal knowledge. Plaintiff bases its belief upon information uncovered through an investigation conducted by and under the supervision of Plaintiff's attorneys into the facts and circumstances alleged herein,

Excluded from the Class are Defendants and their legal representatives, heirs, successors and assigns; the officers, directors and insurers of the Company; members of Termeer's immediate family; and any entity in which any of the foregoing have or had a controlling interest.

including, without limitation, review and analysis of: (a) certain filings made by Genzyme with the U.S. Securities and Exchange Commission ("SEC"); (b) transcripts of Genzyme's analyst and investor conference calls; and (c) publicly available press releases, news articles, and other media reports disseminated by or concerning the Defendants. Except as alleged herein, the underlying information relating to Defendants' misconduct and the particulars thereof are not available to Plaintiff and the public and lie exclusively within the possession and control of Defendants and other Company insiders. Plaintiff believes that further substantial evidentiary support exists for the allegations set forth below and that such support will become available after a reasonable opportunity for discovery.

#### **SUMMARY OF ALLEGATIONS**

- 3. The allegations in this case relate to the operations of Genzyme, a leading biotechnology company based in Cambridge, Massachusetts. The case stems from the Company's concealment of serious issues at two of its manufacturing facilities, which caused a shortage in one of its top-selling products (a drug called Myozyme) and delayed approval of a new formulation of that product (a drug known as Lumizyme). The manufacturing problems also forced the Company to halt production of two other top-selling products (drugs called Cerezyme and Fabrazyme) due to contamination at one of the facilities. These manufacturing issues impacted Genzyme's revenue projections for 2009, and were material information that should have been timely disclosed to investors.
- 4. In the fall of 2008, after two site visits to Genzyme's facility in Allston, Massachusetts (the "Allston facility"), the Food and Drug Administration ("FDA") issued a list of inspection observations, detailing several observations of practices that deviated from the FDA's Good Manufacturing Process ("GMP") standards. Genzyme did not promptly disclose

the FDA's actions, despite the fact that until the problems were corrected, the FDA would not approve Lumizyme, a new version of Myozyme.

- 5. Genzyme also experienced two instances of contamination at its manufacturing plants in the fall of 2008 one in September at Genzyme's facility in Geel, Belgium, and the other in November at the Allston facility. Like the FDA's findings of GMP deviations, these instances of contamination were not disclosed to investors, even though they affected Genzyme's ability to meet consumer demand for Myozyme and led to a supply shortage.
- 6. Genzyme did not disclose the FDA's concerns regarding the Allston facility until March 2, 2009, a full trading day (plus a weekend) after receiving a *second* reprimand titled a "Warning Letter" from the FDA on February 27, 2009. In its March 2 disclosures, Genzyme generally described the manufacturing issues raised by the FDA and notified investors that FDA approval of Lumizyme would be delayed until the FDA's concerns were fully addressed. When this news reached the market, Genzyme's stock fell 7.1%. Even this disclosure, however, did not reveal the contamination problems that had been experienced at the Geel and Allston facilities.
- 7. In April 2009, the impact of the prior contamination issues materialized as Genzyme was unable to manufacture sufficient quantities of Myozyme to meet demand. Genzyme's first quarter earnings came in below analyst expectations, which Genzyme attributed in part to the Myozyme supply constraints, though without disclosing that those supply constraints were a result of contamination problems. This news caused Genzyme's stock price to fall 5.6%, from \$54.50 per share to \$51.34.
- 8. The manufacturing and contamination problems continued, and became increasingly problematic. On June 16, 2009, Genzyme announced that it had detected a virus that impairs cell growth and therefore impedes production of its biologics at its Allston

facility and was suspending production in order to sanitize the facility. The Company's shares fell almost \$3 from a June 15, 2009 close of \$55.62, to close at \$52.75 on June 16, a decline of over 5%.

- 9. On July 22, 2009, Genzyme slashed its earnings and revenue forecasts for 2009, including its revenue projections for Myozyme, Cerezyme and Fabrazyme, due to the impact of the Allston facility shutdown. This announcement resulted in a one-day decline in Genzyme's share price of another \$4.70 per share, or 8.4%.
- 10. From a class period high of \$83.25 per share, Genzyme's stock has fallen over 35% to trade in the low-to-mid-\$50 range. Investors, including Plaintiff, have lost over \$8 billion as a consequence of Defendants' fraudulent misrepresentations about Genzyme's operations and their concealment of negative information, which misled investors regarding Genzyme's potential profitability and growth.

#### **JURISDICTION AND VENUE**

- 11. The claims asserted in this Complaint arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.
- 12. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.
- 13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Genzyme's corporate headquarters are located in this Judicial District and many of the acts and transactions alleged herein occurred in substantial part in this Judicial District.

14. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the United States mails, interstate telephone communications and the facilities of the national securities exchange.

#### THE PARTIES

- 15. Plaintiff Jon Rahn is an individual residing in Wellington, Florida, who purchased Genzyme common stock during the Class Period, as set forth in the attached Certification.
- 16. Defendant Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal executive offices located at 500 Kendall Street, Cambridge, Massachusetts 02142. At all relevant times, the Company's shares traded on the NASDAQ stock exchange under the symbol "GENZ."
- 17. Defendant Termeer was, at all relevant times, Chairman, President, and the Chief Executive Officer of Genzyme. During the Class Period, Termeer was a signatory to Genzyme's Form 10-Q and Form 10-K filings with the SEC, was quoted in Genzyme's press releases, participated in conference calls with securities and market analysts, and made presentations at industry conferences on behalf of Genzyme. By virtue of his high-level positions within the Company, Termeer directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company, its business, operations, finances, and financial condition. Termeer was involved in drafting, producing, reviewing, approving and/or disseminating the materially false and misleading statements and information alleged in this Complaint; knew, or with extreme recklessness, disregarded the fact that materially false and

misleading statements were being issued regarding the Company; and approved or ratified these statements, in violation of the securities laws.

#### **FACTUAL ALLEGATIONS**

#### I. GENZYME'S BUSINESS

- 18. Genzyme was founded as a small start-up in 1981, and has grown into a leading international biotech company, with over 11,000 employees and revenues of \$4.6 billion in 2008. Genzyme's products and services are sold to patients in approximately 100 countries, and are focused on treating rare inherited disorders, kidney disease, orthopedics, transplant and immune disease, and diagnostic testing.
- 19. Many of Genzyme's products are not traditional pharmaceutical products (which are chemically synthesized), but instead are "biologics," a term describing a range of products created from natural sources human, animal, or microorganism and produced through biotechnology methods or other cutting-edge technologies. Biologics tend to be heat sensitive and susceptible to microbial contamination, requiring aseptic principles from initial manufacturing steps.
- 20. This lawsuit stems from manufacturing and contamination issues related to three biologics manufactured by Genzyme's Genetic Disease segment at the Allston facility: Cerezyme, Fabrazyme, and Myozyme.
- \$1.2 billion in 2008. Cerezyme is an enzyme replacement therapy for the treatment of Gaucher disease, the most common of the so-called lysosomal storage diseases. This disease is caused by a hereditary deficiency of the enzyme glucocerebrosidase, which leads to an accumulation of fatty material that can collect in the spleen, liver, kidneys, lungs, brain and bone marrow. It can cause, among other things, liver malfunction, severe neurologic complications and anemia.

- 22. Fabrazyme is Genzyme's third highest revenue generator, bringing in almost \$500 million in 2008. Fabrazyme is a recombinant form of the human enzyme alpha-galactosidase, used for the treatment of Fabry disease, which is caused by the lack of or faulty enzymes needed to metabolize lipids and other fat-like substances. A mutation in the gene that controls this enzyme causes insufficient breakdown of lipids, which build up to harmful levels in the eyes, kidneys, autonomic nervous system, and cardiovascular system.
- 23. Myozyme is the third product at issue in this action, generating \$296 million in 2008. Myozyme is the only available treatment for Pompe disease, a rare genetic disorder in which patients lack an enzyme to break down glycogen, which builds up in certain tissues like the heart and muscles and can lead to heart problems, breathing difficulties and muscle weakness. When Pompe disease occurs early in life, it can progress quickly and is usually fatal without treatment. Thus, treating infants and children who have been diagnosed is a high priority.
- 24. Genzyme initially manufactured Myozyme at the 160 liter ("L") bioreactor scale, and then scaled up the process to produce larger quantities, in larger bioreactors, moving next to the 2000L scale. In April 2006, Genzyme received FDA approval to sell Myozyme produced at the 160L scale in the United States, and also began selling Myozyme produced at the 2000L scale overseas. Soon thereafter, Genzyme sought approval to sell the version produced at the 2000L scale in the United States, but in April 2008 the FDA indicated that Genzyme would be required to submit a separate biologics license application ("BLA") to gain approval for Myozyme produced at the 2000L scale. In the FDA's view, the two versions should be classified as different products because of differences in the carbohydrate structures of the molecules. In

response to the FDA's decision, Genzyme submitted a separate BLA for the 2000L scale version on May 30, 2008, and indicated that this version would be marketed under the name Lumizyme.

# II. GENZYME TOUTS ITS PERFORMANCE BUT CONCEALS MATERIAL FACTS RELATING TO MANUFACTURING AND CONTAMINATION PROBLEMS

- 25. On June 26, 2008, Genzyme made a presentation at the Jefferies Healthcare Conference, which was attended by a number of securities analysts covering Genzyme. During that presentation, a Genzyme executive discussed the positive aspects of Genzyme's business, including significant growth in sales of Cerezyme, Fabrazyme and Myzozyme. However, as Defendants knew or recklessly failed to discover at that time, Genzyme's manufacturing practices for those products were not in compliance with FDA regulations concerning good manufacturing practices ("GMPs"). This non-compliance presented material risks to the future of Genzyme's business, but was not disclosed.
- In a press release dated July 23, 2008, Genzyme posted strong results and touted its strength. The Company reported a 25% increase in revenue to approximately \$1.171 billion from \$933.4 million in the prior year's second quarter and announced that "[t]he increase was driven by growth across all areas of the business." Defendant Termeer stated that "[i]t was a strong and highly productive quarter." Much of the success was attributed to strong sales of Myozyme. The July 23 press release also stated that the Company expected to get FDA approval by the end of 2008 for the new form of Myozyme (*i.e.*, Lumizyme) and approval of the European Medicines Evaluation Agency ("EMEA") in the first half of 2009 for production of Myozyme at the 4000L scale, including approval for production at the Company's plant in Belgium. The July 23 press release further stated that Cerezyme and Fabrazyme "continue[d] to experience strong, double-digit growth" as second quarter sales of Cerezyme rose 13% to \$319.4 million, compared

with \$283 million in the previous second quarter, and second quarter sales of Fabrazyme grew 21%, rising to \$126.6 million from \$104.3 million. Once again, Defendants did not disclose the Company's ongoing non-compliance with GMPs.

- 27. In the fall of 2008, Genzyme again reported strong results, with third-quarter revenue at \$1.160 billion, a 21% increase from the third quarter of 2007. In a press release dated October 22, 2008, Termeer noted that the "third quarter was a very strong quarter financially and also extremely productive in terms of building for the future" and that Genzyme's "broad geographic diversification, solid cash position, and group of market-leading products will allow us to sustain our growth through the current financial environment and over the longer term." Genzyme noted that one catalyst for revenue growth over the next several quarters would be the FDA approval of the 2000L scale version of Myozyme, *i.e.*, Lumizyme, expected by November 29, 2008, and that the absence of this approval had constrained sales of Myozyme to that point. Genzyme also reported that it was seeking approval from European regulators for 4000L production, which it anticipated it would receive in the first half of 2009. In the meantime, the Company indicated that "supply is expected to remain tight." Genzyme reported similar figures and projections regarding Myozyme and Lumizyme in its Form 10-Q for the third quarter of 2008, filed on November 7, 2008.
- 28. Genzyme's October 22, 2008 press release again did not disclose its GMP violations, despite the fact that from September 15 through October 10, 2008, FDA officials had conducted a GMP inspection at the Allston facility. In the resulting write-up, known as "Inspectional Observations" (formally, a Form FDA 483), the FDA noted significant deviations from GMP compliance, including observations relating to Genzyme's procedures designed to prevent microbiological contamination of sterile drug products, controls for in-process

monitoring during bulk drug substance manufacturing, and maintenance of equipment. This Form FDA 483 was sent to Termeer on or about October 10, 2008. Genzyme responded to the FDA on October 31, 2008 with a plan and timeline to address the Inspectional Observations, with the aim of resolving all the issues by March 31, 2009. None of this activity was reported to the public, including in the October 22, 2008, press release or the third quarter 10-Q, despite the fact that a failure to cure the violations could impact Genzyme's ability to continue its operations at the Allston facility, which in turn would impact Genzyme's revenue and profitability.

- 29. The October 22, 2008 press release also failed to disclose that, in September of 2008, Genzyme had discovered a problem at its plant in Geel, Belgium, when, for unknown reasons, cell productivity declined, which impacted its ability to manufacture Myozyme on time. This contributed to Genzyme's "tight" supply of Myozyme, but was not disclosed in the Company's press releases or SEC filings during 2008. Instead, Genzyme misleadingly implied that the shortage was the result of a growth in demand that had outpaced the growth in supply, *not* the result of manufacturing problems.
- 30. In early 2009, the Company posted strong results for the fourth quarter of 2008 and provided continued assurance for investors about the Company's prospects. At the JPMorgan 27<sup>th</sup> Annual Healthcare Conference in San Francisco, Termeer presented preliminary, unaudited figures for the fourth quarter of 2008 and the full year. He announced that revenue had risen 13% in the fourth quarter of 2008 and 21% for the year. The Company also reported these results in a press release dated January 13, 2009.
- 31. In the January 13 press release, the Company informed the public of a delay in FDA approval of Lumizyme, which it now expected to receive by February 28, 2009. Despite this delay, fourth quarter Myozyme revenue had increased to \$75 million, a 20% increase over

the \$62 million reported in the fourth quarter of 2007. Looking at the year as a whole, Myozyme revenue grew from \$201 million in 2007 to \$296 million in 2008 – an increase of almost one-third. The Company also stated that it had submitted the application to the EMEA for approval of the 4000L scale Myozyme product to be manufactured at the Company's Belgium manufacturing plant on December 22, 2008, and that it had sought expedited review of that application. Genzyme's January 13 press release also reported further strong results for Cerezyme (with sales up \$5 million over the fourth quarter in 2007 and up \$100 million over the prior year) and Fabrazyme (with sales up 10% over the fourth quarter in 2007 and up 17% over the prior year), and announced that "[r]evenues for 2009 are expected to be between \$5.2 billion and \$5.4 billion."

32. Genzyme failed to disclose, however, the FDA issues regarding Genzyme's non-compliance with GMP at its Allston facility, or the contamination problems at the Geel, Belgium facility. Nor did Defendants disclose that, in November 2008, Genzyme had experienced the same slow-down in cell growth at the Allston facility that it had experienced in the Geel facility a few months earlier. As a result of these events, Genzyme was unable to produce the expected quantities of Myozyme, creating the possibility of an upcoming shortage. In its January 13, 2009, press release, Genzyme noted that inventory levels of Myozyme were "expected to be so tight that there [was] a risk of delays in order fulfillment and consequent interruptions in therapy," but the Company was still silent about the actual cause of the supply constraints – the problems at the Geel and Allston facilities. Instead, Genzyme continued to attribute the problem to strong global demand and the fact that it had not yet received EMEA approval to scale up production with the 4000L process.

# III. THE FIRST IMPACT OF THE CONCEALED MANUFACTURING PROBLEMS COMES TO LIGHT

33. In January 2009, the first hints of problems at Genzyme's manufacturing facilities began to emerge in the press. On January 20, 2009, an article in *TheStreet.com* reported:

European regulators have recommended rationing of a Genzyme...drug to treat a rare genetic disorder *due to unspecified manufacturing problems*.

The...EMEA said Friday that infants, children and adolescents with Pompe disease should be given priority access to Genzyme's Myozyme due to a supply shortage that is expected to last several months.

The EMEA said the Myozyme shortage was caused by an increase in demand for the drug as well as unspecified manufacturing problems at some sites where Genzyme makes the drug.

Deutsche Bank biotech analyst Mark Schoenebaum said the new Myozyme manufacturing issues disclosed by the EMEA Friday could reduce Myozyme to equal or below fourth-quarter 2008 levels.

"The EPE impact should be modest given Genzyme's ability to manage expenses," he added. Schoenebaum ha[d] a hold rating on Genzyme.

Adam Feuerstein, "Genzyme Drug Rationing Urged Amid Shortage, *TheStreet.com*, Jan. 20, 2009 (emphasis added).

34. In a press release issued on February 11, 2009, Genzyme announced its final fourth-quarter and full-year figures for 2008 and provided projections for 2009. Termeer noted that the Company "had an excellent year last year and exceeded [its] earnings expectations despite the economic environment and the challenges [it] faced with Myozyme." For Myozyme, the Company projected that revenue would increase to \$430-\$440 million, up from \$296 million in 2008. In particular, Genzyme anticipated that earnings would accelerate during the second quarter, assuming the awaited regulatory approvals from the FDA and EMEA were secured. Genzyme also projected that revenue from Fabrazyme would increase from \$494 million in 2008

to \$560-\$570 million in 2009, and that revenue from Cerezyme would increase from \$1.24 billion in 2008 to \$1.25-\$1.28 billion in 2009.

- 35. During the afternoon of Friday, February 27, 2009, the Company received two letters from the FDA. In one letter, which was addressed to Termeer and titled "Warning Letter," the FDA conveyed its ongoing concerns regarding GMP compliance at the Allston facility. In the other letter, the FDA indicated that it would not approve Lumizyme by the expected February 28 deadline and would withhold approval until the issues identified regarding the Allston facility were resolved. Genzyme made no public disclosures regarding either letter by the end of the day.
- 36. By the close of trading on Monday, March 2, 2009, the Company still had not disclosed the contents or existence of the FDA's letters. However, at 4:23 p.m. after the market close Genzyme issued a press release regarding the FDA letters and announced a conference call on the subject to be held at 5:00 p.m. At 4:48 p.m., Genzyme filed its Form 10-K with the SEC, which stated:

In September and October 2008, FDA officials conducted a Good Manufacturing Practices, or GMP, inspection of licensed therapeutic drug products, bulk drug substances and drug components manufactured at our Allston, Massachusetts facility. We manufacture Cerezyme, Fabrazyme and Myozyme and perform fill/finish for Aldurazyme and Thyrogen at this facility. After this inspection, the FDA officials issued a list of inspection observations known as a Form FDA 483. The form detailed inspectional observations considered by the FDA to be significant deviations from GMP compliance, including observations relating to our procedures designed to prevent microbiological contamination of sterile drug products; controls for in-process monitoring during bulk drug substance manufacturing, including our controls for bioburden monitoring; and maintenance of equipment and computer systems validation. We responded to the Form FDA 483 on October 31, 2008 with a plan and timeline to address the inspectional observations and provided a progress update on February 23, 2009 to the FDA. On February 27, 2009, we received a warning letter from the FDA that requested supplemental information in order to fully evaluate the adequacy of our corrective actions with respect to nine of the FDA's sixteen observations in the Form FDA 483. We currently are reviewing the warning letter and plan to

respond to the FDA in writing within fifteen business days of receipt of the letter as is required. We are committed to working cooperatively with the FDA regarding this matter. The issuance of the warning letter does not affect the continued distribution of our Genetic Diseases products currently on the market or our inventory currently on hand. We believe that the products produced at our Allston facility continue to meet the highest quality and safety standards.

Failure to correct the deviations cited in the FDA's warning letter could result in further regulatory action, including suspension of our license to manufacture products at the facility, or lead to a delay in the approval of new products. The FDA will not approve our application to market alglucosidase alfa produced at the 2000L scale [i.e., Lumizyme] at our Allston facility until the issues identified in the warning letter are resolved to the FDA's satisfaction.

Thus, Genzyme finally revealed for the first time that the FDA had found significant problems at the Allston facility, that these issues were the subject of ongoing discussions with the FDA, and that these issues created another obstacle delaying approval of Lumizyme.

- 37. However, Genzyme's March 2 disclosures were materially incomplete. Neither the press release nor the 10-K mentioned the contamination that had occurred at Genzyme's Geel and Allston facilities in the fall of 2008, which had disrupted the supply of Myozyme, impacting revenue for the first quarter of 2009.
- 38. In light of the developments with the FDA, and assuming a six-month delay in obtaining FDA approval for Lumizyme, Genzyme stated in its March 2 press release that its revised projections for Myozyme revenue in 2009 were in the range of \$370-\$380 million, down from the projections of \$430-\$440 million announced just a few weeks earlier.
- 39. On this news, Genzyme shares dropped over 6% in after-market trading on March 2, down to \$53 from its closing price of \$56.52.
- 40. On March 3, 2009, with a full day of trading to absorb the belatedly-disclosed news, Genzyme's shares closed at \$52.48, a total drop of \$4.04 per share (more than 7%) from their March 2 close, on high trading volume twice the volume of March 2.

41. On March 3, 2009, the financial press noted that Genzyme had kept material information secret from investors for three days:

Genzyme waited three days, including one trading day in which its stock dropped, before disclosing to investors that the [FDA] is delaying a key product.

The Cambridge, Mass.-based biotechnology firm said on a conference call Monday that it had received two letters from the FDA on Friday afternoon....

But Genzyme did not disclose the existence of the two letters until late Monday, after trading on the Nasdaq had stopped....

When Genzyme did disclose the news, it said the delay would lower its 2009 profit by about 12 cents per share. Shares dropped another 5% [sic] in aftermarket trading.

"One would definitely have thought" the company had a duty to disclose the news earlier, says Geoffrey Porges, a biotechnology analyst at Sanford C. Bernstein. "People do read press releases over the weekend as well," Porges says.

"We needed the opportunity to talk through the feedback with the FDA, and put together our communication," says Lori Gorski, a Genzyme spokeswoman. Gorski declined to say whether the communication with the FDA came before or after the market closed on Friday.

Matthew Herper, "Genzyme Held Bad News as Shares Dropped," Forbes.com, Mar. 3, 2009 (emphasis added).

- 42. The *Forbes* article also raised the possibility that news of the FDA's letters had been leaked, given that the Company's share price fell before the news was announced. "Genzyme shares dropped 4% on Friday, followed by another 7% drop on Monday. . . . The drop outpaced the fall of the broader market and of biotech stocks." *Id*.
- 43. On March 11, 2009, *The Wall Street Journal* published excerpts of a redacted copy of the FDA's February 27, 2009 warning letter, which it had obtained from the FDA. The article stated:

[FDA] investigators found "significant objectionable conditions" during an inspection of [the Boston plant].

The Feb. 27 letter outlines a number of deficiencies in the manufacturing process at the Boston plant....

FDA investigators inspected the plant from Sept. 15, [2008] through Oct. 10, [2008] and "documented significant deviations from current good manufacturing practice."

\* \* \*

Much of the six-page letter involves technical critiques of the manufacturing process.

"The deficiencies described in this letter are indicative of your quality control unit's failure to fulfill its responsibility to assure the identity, strength, quality and purity of your drug products and drug substances," the letter says.

For instance, the FDA said Genzyme failed to perform maintenance on large aluminum freezers used to transport cell banks and was using freezers – called cryoshippers – beyond their stated life expectancy. [Genzyme Vice President Mark] Bamforth says the company has changed its procedures following the inspection.

David Armstrong, "FDA Warns Genzyme on Plant Conditions," *The Wall Street Journal*, Mar. 11, 2009 (emphasis added). The article further states that Bamforth "said the company has addressed 80% of the problems cited by the FDA and expects to resolve all of the issues by the end of April.... He said the Boston plant continues to produce treatments and that 'the efficacy and safety of our products is unchanged." *Id*.

44. In reaction to the article and despite Bamforth's reassurances, on March 11, 2009, Genzyme's stock price dropped \$2.37 per share, or 4.3%, to close at \$52.82. Still, however, the contamination problems that had been experienced in the Geel and Allston facilities remained undisclosed to investors.

## IV. THE IMPACT OF THE MANUFACTURING PROBLEMS HITS GENZYME'S BOTTOM LINE

- 45. On April 22, 2009, Genzyme reported growth in first quarter earnings, but its profit and revenue fell below Wall Street expectations. In particular, revenue for the quarter rose from \$1.10 billion in 2008 to \$1.15 billion a 4% increase but far less than the \$1.21 billion consensus revenue estimate. Genzyme said revenue in the quarter was impacted by negative currency exchange rates and a slowdown in sales of Myozyme due to supply constraints. Once again, Defendants did not disclose that these supply constraints were attributable to contamination problems that had occurred during the fall of 2008, which had still not been disclosed. Myozyme sales totaled \$67.4 million in the first quarter, essentially flat with the prior year period's \$67.3 million, and well below the analysts' consensus estimate of \$91 million. At this rate, Myozyme revenues would total approximately \$270 million for the year, well below the \$370-\$380 million forecasted in March. The Company nevertheless reaffirmed its revenue and earnings guidance for 2009.
- 46. In reaction to this news, the Company's stock price fell 5.6% to close at \$51.34 per share on April 22, 2009, the lowest price during the Class Period.

# V. <u>GENZYME APPEARS TO RECOVER FROM ITS MYOZYME</u> <u>PROBLEMS</u>

47. On May 6, 2009, Genzyme held an Analyst Day Meeting and issued updated business guidance in conjunction with this meeting. Genzyme announced that the FDA had indicated that it would review the Company's submission regarding items specific to the Lumizyme application and would not require inspection of the Allston facility before initiating that review. Nonetheless, it was likely to be roughly six months before the approval process would be complete – a nine-month delay compared to the previous target of February 28, 2009. Despite this setback and the tepid growth in Myozyme sales in the first quarter of the year

(resulting from the shortage), Genzyme reaffirmed its revenue guidance of \$5.15-\$5.35 billion for 2009.

48. On May 21, 2009, Genzyme reported that it had submitted the final documentation to address the FDA's outstanding items with respect to the Lumizyme application. Additionally, the Company stated that it had completed the measures required to respond to the FDA's warning letter regarding the Allston facility. Genzyme indicated that the FDA had begun inspection of the plant to determine if the deficiencies cited in its warning letter had been addressed to its satisfaction.

### VI. PRODUCTION PROBLEMS RETURN AND CAUSE A SHUT-DOWN OF THE ALLSTON FACILITY AND FURTHER REVENUE LOSSES

- 49. On June 16, 2009, Genzyme announced that it had detected a virus that impairs cell growth in one of six bioreactors at the Allston facility. The virus strain, Vesivirus 2117, is not known to cause human infection but interferes with the growth of cells used in the manufacturing process. The FDA's February 27, 2009 Warning Letter had foreshadowed that such contamination was possible, noting that "[i]nternal surfaces . . . used during drug substance purification are not adequately maintained. Maintenance has never been performed on the interior of columns to prevent *adverse impact on cell cultures* due to metal contamination." (emphasis added).
- 50. The Company decided to halt all production at the Allston facility in order to sanitize it. As a result, the Company would have to suspend production of Cerezyme and Fabrazyme, which were manufactured at the Allston facility, causing supply constraints in both products and a need for temporary rationing. For Cerezyme, Genzyme stated that it expected the shortage to occur in August, for a one-month duration. For Fabrazyme, Genzyme stated that it expected the shortage to occur in mid-September, and to last in the six-to-eight week range.

- 51. The Company also announced that it was able to confirm that this virus had caused the decline in productivity at the Allston and Geel facilities in the fall of 2008. In other words, the same virus that had caused shortages of Myozyme in the first quarter of 2009 was now causing shortages of two of Genzyme's top three revenue-producing products. This was the *first* public disclosure of the prior contamination incidents.
- 52. The Company acknowledged that its bottom line would be impacted by the contamination issues at the Allston facility, stating that it would provide updated financial guidance as soon as possible. Karen Andersen of Morningstar estimated that sales of Cerezyme and Fabrazyme could each be depressed by as much as \$150 million, totaling a 6% hit to total revenue.
- 53. The Company's shares fell almost \$3 from a June 15, 2009 close of \$55.62 to close at \$52.75 on June 16, a drop of nearly 5.5%, on heavy trading volume (approximately 17 million shares, compared to roughly 6 million the day before).
- 54. On June 25, 2009, Genzyme provided an update on the decontamination process and the extent of the projected shortages. As of late June, Genzyme expected sales of both products to be interrupted for six to eight weeks (compared to the initial projection of only a one-month disruption for Cerezyme). Mark Schoenebaum, senior biotech analyst at Deutsche Bank, projected that the shutdown would lower Genzyme's revenue by approximately \$245 million, while he had previously estimated it would only cost \$100 million.
- 55. On the morning of July 22, 2009, Genzyme announced that it was lowering its 2009 earnings forecast from \$3.52 per share to a range of \$2.35 to \$2.90 per share, due to the shutdown of its Allston facility. The Company noted that the shutdown had cut revenue by \$13 million during the quarter ended June 30, 2009, but would have an even greater impact on

Genzyme's business during the second half of 2009. Due to product shortages caused by the shutdown, Genzyme lowered its full-year revenue projections for Cerezyme (to a range of \$750 million to \$1 billion, from a prior forecast of \$1.25 billion to \$1.275 billion), Myozyme (to a range of \$330 million to \$340 million from a previous range of \$370 million to \$380 million), and Fabrazyme (to a range of \$510 million to \$520 million, from a prior forecast of \$560 million to \$570 million). In total, the Company reduced its 2009 revenue projections to between \$4.6 billion and \$5 billion, down from a previous estimate of \$5.15 billion to \$5.35 billion. In response, to this announcement, Genzyme's share price dropped sharply to close at \$51.21 on July 22 – a decline of \$4.70 per share, or 8.4%, from the prior day's close.

56. The full damage arising out of the virus contamination and the FDA's concerns regarding the Allston facility has yet to be seen.

#### DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

- 57. The following statements by Defendants during the Class Period, among others, were false and/or misleading.
- 58. During a June 26, 2008 investor conference and in a July 23, 2008 earnings release, Genzyme made bullish statements about its products and their historical and expected future growth. At the time of those statements, Defendants either knew or recklessly failed to discover that the Company was deviating from GMPs in material respects and that its ability to realized continued growth was therefore at risk. These deviations were material information to investors, as they significantly affected the Company's future business prospects. However, this information was not disclosed, and Genzyme gave no indication of any potential impediments to the growth it was projecting.

59. On October 22, 2008, Genzyme issued a press release entitled "Genzyme Reports Strong Third-Quarter Sales and Earnings Growth." The press release stated in part:

Genzyme is also preparing to seek clearance from European authorities for 400L-scale production of Myozyme at its manufacturing facility in Belgium. The company has successfully completed the required three consecutive process validation runs. In addition, preliminary data on the comparability of 4000L product with 2000L product are encouraging. Genzyme anticipates submitting an application for 4000L production in early January, and EMEA approval is anticipated during the first half of next year. Approval of 4000L-scale production will be necessary to meet the anticipated global demand for Myozyme. **Product supply is expected to remain tight until the 4000-L process is approved.** 

(emphasis added).

- 60. Defendants' statements in the October 22, 2008 press-release omitted material information regarding the likelihood of a Myozyme shortage and the cause of such a shortage. Specifically, Defendants omitted information regarding the incident with the Vesivirus 2117, which had necessitated a shut-down of Myozyme production at the Geel facility in September 2008 and exacerbated the shortage that Genzyme had previously disclosed. Thus, investors were unaware of the increased risk that the Company could not meet its sales and growth projections for Myozyme in the first part of 2009.
- 61. Defendants also omitted information regarding the FDA's findings that the Allston facility failed to comply with GMP in numerous respects, including procedures designed to prevent microbiological contamination of sterile drug products, such as the contamination that had just occurred. Defendants also omitted the fact that failure to address the FDA's concerns could impact its license to manufacture products at the Allston facility and approval of other products, including Lumizyme. Investors had no knowledge that Genzyme's ability to continue manufacturing its top-selling and fastest-growing products was subject to these substantial and imminent risks, in turn jeopardizing its forecasted growth and profitability. Without the

information regarding the contamination incidents and the FDA's concerns, investors could not incorporate these risks into their decisions to purchase and/or retain Genzyme stock.

62. Genzyme filed its Form 10-Q for the third quarter of 2008 on November 7, 2008. This filing stated in part:

We expect the FDA to act on the [Lumizyme] BLA by November 29, 2008. We anticipate that this process will culminate in the availability of two commercial versions of alglucosidase alfa in the United States...We expect demand for Myozyme to continue to grow and expect to begin providing U.S. patients with commercial 2000L product during the first quarter of 2009.

To meet global demand for Myozyme, we are working to secure approval from the EMEA to produce Myozyme at our 4000L scale manufacturing facility in Belgium. We have successfully completed the required three consecutive process validation runs for Myozyme produced at the 4000L scale and we expect to file for EMEA approval of the 4000L production in January 2009. We anticipate EMEA approval during the first half of 2009. Approval of 4000L scale production will be necessary to meet the anticipated global demand for Myozyme. **Product supply of Myozyme is expected to remain tight until the 4000L process is approved**.

(emphasis added).

- 63. Like the October 22, 2008 press release, Defendants' statements in the third-quarter 10-Q omitted material information regarding the shut-down of the Geel facility that had impacted Myozyme production and the FDA's findings regarding Genzyme's compliance with GMP at its Allston facility, which threatened the projected schedule for Lumizyme approval and production of any biologics at the Allston facility. The 10-Q thus understated the risks that Genzyme could not meet its revenue targets for 2009, thereby contributing to the Company's inflated stock price.
- 64. On November 17, 2008, the Company issued a press release entitled "Myozyme Produced at the 2000 L Bioreactor Scale to Receive Accelerated Approval." In this press release, Genzyme explained that the FDA was reviewing the Company's Risk Evaluation and

Mitigation Strategy for the Lumizyme BLA and that the agency viewed the submission as a major amendment to the BLA. The FDA had therefore extended the anticipated approval date by 90 days to February 28, 2009. Defendants' statements in this press release omitted material information regarding the FDA's write-up of GMP issues at the Allston facility, which threatened the approval schedule for Lumizyme, as well as Genzyme's ability to operate that facility overall. Genzyme conveyed the impression of nothing more than a routine, 90-day delay, which would not have significant implications for its projected Myozyme sales. In reality, however, Defendants knew that Genzyme had to remedy the non-compliance quickly to avoid additional delays in the Lumizyme approval or delays in producing the other therapies manufactured at the Allston facility. Investors were unaware of these problems for months and accordingly, could not properly assess the value of Genzyme's stock.

65. On January 13, 2009, the Company issued a press release entitled "Genzyme Reports Strong Fourth-Quarter and 2008 Revenue Growth." The press release stated in part:

On December 22, Genzyme submitted an application to the European Medicines Evaluation Agency seeking approval to produce Myozyme at the 4000 L scale at its manufacturing facility in Geel, Belgium. The 4000 L manufacturing process is expected to provide adequate supply to meet the strong global demand for Myozyme for the foreseeable future. Under the standard review process, action by the European Commission would be expected in April. Genzyme has requested expedited review of its application. The company anticipates filing for U.S. approval for the 4000 L manufacturing process during the first half of this year. From January through April of this year, *inventory levels are expected to be so tight that there is a risk of delays in order fulfillment* and consequent potential interruptions in therapy.

(emphasis added).

66. Defendants' statements in the January 13, 2009 press-release omitted material information regarding the likelihood of a Myozyme shortage and the cause of such a shortage. Defendants again omitted information regarding the two incidents with the Vesivirus 2117 which

had necessitated shut-downs of Myozyme production, once at the Geel facility in September 2008 and again at the Allston facility in November of 2008. Defendants were already aware that such a shortage had developed, as became evident by the EMEA guidance issued the next week regarding how to ration the treatment during the shortage, yet only stated that there was a "risk" of delays in fulfillment. Investors did not know that this risk had already materialized and would impact Myozyme sales for the first quarter of 2009. They would only find out in April, after having made further investment decisions with respect to Genzyme shares based on the Company's misleading depiction of the risk of a Myozyme shortage.

- 67. Defendants also again omitted information regarding the FDA's findings that the Allston facility failed to comply with GMP and that failure to address the FDA's concerns could impact its license to manufacture products at the Allston facility and approval of other products, including Lumizyme. Investors were again deprived of information necessary to assess Genzyme's likely revenue gains and profitability and the appropriate value of its stock.
- 68. After Genzyme received the two FDA letters on February 27, 2009 (regarding Lumizyme and the Allston facility), Genzyme made **no** disclosure at all until after trading closed on March 2, 2009, after a full day of trading. Even then, Defendants still failed to disclose the incidents with Vesivirus 2117 that had occurred at its facilities in the fall of 2008 and had caused a shortage of Myozyme, again leaving investors with an incomplete picture of the risks that the Company could miss its revenue targets for the year.
- 69. On April 22, 2009, Genzyme issued a press release entitled "Genzyme Reports Solid Financial Results for the First Quarter of 2009." In that press release, the Company disclosed that Myozyme sales had barely increased compared to the first quarter of 2008 due to a "global supply management program under which adults with Pompe disease temporarily missed

doses in order to preserve constrained supply for infants and children." The Company also disclosed that it had received European regulatory approval for Myozyme production at the 4000L scale and reported on its progress in FDA approval of Lumizyme. However, Defendants again omitted the cause of the supply constraint – the two factory shut-downs during the fall of 2008. This omission, coupled with the extensive discussion of the Company's upcoming efforts to increase supply of Myozyme, created the false impression that the Company was not responsible for the shortage.

70. Genzyme filed its Form 10-Q for the first quarter of 2009 on May 8, 2009. This filing stated in part:

Sales of Myozyme were virtually the same for the three months ended March 31, 2009, as compared to the same period of 2008. Although sales of Myozyme increased for the three months ended March 31, 2009, due to the identification of new patients following European approval of product produced at the 4000L scale in February 2009, the growth in sales of Myozyme was adversely affected by the product not yet being approved for promotion in the U.S. market and by a global supply management program under which adult Pompe disease patients temporarily adjusted their infusion schedules in order to preserve constrained product supply for infants and children.

(emphasis added).

71. As with the April 22, 2009, press release, Defendants' statements regarding Myozyme in the 10-Q for the first quarter of 2009 conveyed the false impression that the Myozyme shortage resulted from regulatory delays that were preventing Genzyme from keeping up with increasing demand. The 10-Q omitted the material information regarding the Vesivirus 2117 occurrences, which had forced shut-downs of the Geel and Allston facilities and caused the supply constraints that developed early in 2009. Thus, investors could not yet see that problems with contamination at Genzyme's facilities had already impacted its output and sales, *i.e.*, that

the FDA's concerns with the Company's GMP non-compliance presented more than a hypothetical risk to its profitability.

72. With respect to each of the false and/or misleading statements and omissions set forth in the foregoing paragraphs, the facts that were misrepresented and/or omitted by Defendants were material to the investment decisions of Genzyme's investors because, among other reasons, they downplayed the likelihood that the Company would miss its revenue targets.

#### **LOSS CAUSATION**

- 73. Throughout the Class Period, Defendants' materially false and misleading statements and omissions concerning Genzyme's supply and manufacturing issues and projected earnings caused Genzyme's stock price to be inflated. As a result of Defendants' false and misleading statements and material omissions, Genzyme's common stock traded between \$70 per share and \$80 per share for most of the Class Period, reaching a Class Period high of \$83.25 on August 14, 2008.
- Plaintiff and the other members of the Class suffered damages as a direct result of Defendants' fraudulent conduct described in this Complaint. But for Defendants' misrepresentations and omissions, Plaintiff and the members of the Class would not have purchased Genzyme's stock, or would not have purchased it at artificially inflated prices. When the reality of Defendants' conduct and the true picture of Genzyme's manufacturing operations and revenue projections were revealed to the investing public, the price of Genzyme common stock declined significantly, as described above, causing damages to Plaintiff and other Class members.

#### ADDITIONAL ALLEGATIONS OF SCIENTER

75. The Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued by them were materially false and/or

misleading; knew or recklessly disregarded the fact that such statements would be disseminated to the investing public; and knowingly and substantially participated in the issuance and dissemination of the public documents and statements. In addition, Defendants acted with scienter by intentionally failing to inform the market in a timely manner of material information. Defendants' intent to deceive and/or reckless disregard for the truth is demonstrated by direct evidence as well as circumstantial evidence supporting a strong inference of scienter.

76. Termeer was an active and culpable participant in the management of Genzyme, which involved ensuring that its manufacturing facilities were operating properly in order to sustain supply for its products and that any regulatory requirements impacting the manufacturing facilities had been met. Termeer was aware of the Company's contamination problems at the Geel and Allston facilities during the fall of 2008, and he either knew of should have known no later than June 26, 2008 about the GMP deviations that would later be set forth in the Form FDA 483 in October 2008. As the recipient of the Form FDA 483, he was unquestionably aware of the GMP deviations discussed therein by October 10, 2008. Termeer knew – or was reckless in not knowing – that the supply of Myozyme was at risk and that violations of the FDA's GMPs would jeopardize the Company's ability to continue making its products and obtain approval of Lumizyme. However, Termeer failed to disclose these problems, or their potential impact on Genzyme's financial results and operations, to investors in a timely fashion.

#### **CLASS ACTION ALLEGATIONS**

77. Plaintiff brings this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of Plaintiff and a Class consisting of all those who purchased common stock of Genzyme between and including June 26, 2008 and July 21, 2009 and who were damaged as a consequence. Excluded from the Class are Defendants and their legal representatives, heirs, successors and assigns; those who were officers, directors or

insurers of Genzyme during the Class Period; members of Termeer's immediate family; and any entity in which any of the foregoing have or had a controlling interest.

- 78. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Genzyme's common stock was actively traded on the Nasdaq stock exchange. According to the Company's 2008 Form 10-K, there were 271,352,703 shares of Genzyme common stock outstanding as of January 31, 2009. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Genzyme or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.
- 79. Plaintiff's claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws.
- 80. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.
- 81. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
- a. whether the federal securities laws were violated by Defendants' conduct as alleged in this Complaint;

- b. whether statements made by Defendants to the investing public during the Class Period misrepresented and/or omitted material facts about the business, operations and profitability of Genzyme;
- c. whether reliance upon Defendants' misrepresentations and/or omissions may be presumed;
  - d. whether Defendants acted with scienter; and
- e. to what extent the members of the Class have sustained damages and the proper measure of damages.
- 82. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impracticable for members of the Class to individually redress the wrongs done to them. Plaintiff anticipates no difficulty in the management of this action as a class action.

### APPLICABILITY OF PRESUMPTION OF RELIANCE: THE FRAUD-ON-THE-MARKET DOCTRINE

- 83. At all relevant times, the market for Genzyme's common stock was an efficient market for the following reasons, among others:
- a. Genzyme's stock met the requirements for listing, and was listed and actively traded on the Nasdaq stock exchange, a highly efficient and automated market;
- b. During the Class Period, the average weekly trading volume of Genzyme's stock was greater than two percent of the outstanding shares, justifying a strong presumption that the market for Genzyme's shares was efficient;

- c. As a regulated issuer, Genzyme filed periodic public reports with the SEC and the Nasdaq stock exchange;
- d. Genzyme regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- e. Genzyme was followed by over twenty securities analysts who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;
- f. There was a cause-and-effect relationship between unexpected corporate events or financial releases and movements in the stock price; and
- g. Genzyme was eligible to register its stock pursuant to a Form S-3 registration statement.
- 84. The market for Genzyme's common stock promptly digested current information regarding Genzyme from all publicly-available sources and reflected such information in Genzyme's stock price. Under these circumstances, it is appropriate to presume that all purchasers of Genzyme common stock during the Class Period relied on the misstatements and omissions by Defendants.

#### **COUNT I**

#### AGAINST ALL DEFENDANTS FOR VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5

85. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein.

- 86. This Claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, on behalf of Plaintiff and all other members of the Class against all Defendants.
- 87. As alleged in this Complaint, throughout the Class Period, Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of a national securities exchange, made false and/or misleading statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Among other things, Genzyme's SEC filings and press releases contained materially false and/or misleading statements of fact and/or omitted material facts as detailed above.
- 88. Defendants' false and misleading statements and omissions were intended to and did, as alleged herein, (i) deceive the investing public, including Plaintiff and the other members of the Class; (ii) artificially inflate and maintain the market price of Genzyme's securities; and (iii) cause Plaintiff and the other members of the Class to purchase Genzyme's securities at inflated prices.
- 89. Defendants were each individually and collectively responsible for making one or more of the statements and omissions alleged herein, by virtue of having prepared, reviewed, commented on, approved, signed, and/or disseminated documents which contained false and/or misleading statements of material fact and/or omitted facts necessary to make the statements therein not misleading.
- 90. Defendants made the false and/or misleading statements and omissions knowingly and intentionally, or in such an extremely reckless manner as to constitute willful deceit and

fraud upon Plaintiff and other members of the Class who purchased Genzyme's common stock during the Class Period.

- 91. Defendants' false and/or misleading statements and omissions were made in connection with the purchase or sale of Genzyme's common stock.
- 92. In ignorance of the false and misleading nature of Defendants' statements and omissions, and relying directly or indirectly on those statements and/or upon the integrity of the market price for Genzyme's common stock, Plaintiff and the other members of the Class purchased Genzyme's common stock at artificially inflated prices during the Class Period. But for the fraud committed by the Defendants, Plaintiff and the members of the Class would not have purchased these securities at artificially inflated prices.
- 93. The market price for Genzyme's common stock declined materially upon the public disclosure of the facts that had previously been misrepresented or omitted by Defendants, as described above.
- 94. Plaintiff and the other members of the Class were substantially damaged as a direct and proximate result of their purchases of Genzyme's common stock at artificially inflated prices and the subsequent decline in the price of those securities when the truth was revealed.

#### **COUNT II**

#### AGAINST TERMEER PURSUANT TO SECTION 20(a) OF THE EXCHANGE ACT

- 95. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein.
- 96. This Claim is brought on behalf of Plaintiff and all other members of the Class against defendant Termeer, pursuant to Section 20(a) of the Exchange Act.

- 97. Throughout the Class Period, Termeer was a controlling person of Genzyme within the meaning of Section 20(a) of the Exchange Act. By virtue of his positions as President, Chief Executive Officer and Chairman of the Board of Directors of Genzyme, Termeer had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Genzyme, including the content and dissemination of the various statements that Plaintiff contends are materially false and misleading. Termeer was provided with or had unlimited access to copies of Genzyme's press releases and public filings alleged by Plaintiff to be false and/or misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements, cause the statements to be corrected, or cause the statements to be made at an earlier time.
- 98. As set forth above, Genzyme violated Section 10(b) and Rule 10b-5 by its acts and omissions as alleged herein. As a direct and proximate result of Genzyme's wrongful conduct, Plaintiff and the Class suffered damages. As a controlling person of Genzyme, Termeer is liable pursuant to Section 20(a) of the Exchange Act for Genzyme's violations of Section 10(b) and Rule 10b-5.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment:

- A. Determining that this action is a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding compensatory damages against Defendants in favor of Plaintiff and all Class members for damages sustained as a result of Defendants' wrongdoing;
- C. Awarding Plaintiff and all Class members their costs and disbursements in this suit, including reasonable attorneys' fees and expert fees; and
  - D. Awarding such other relief as the Court deems just and proper.

#### **JURY DEMAND**

Plaintiff, on behalf of itself and the Class, hereby demands a trial by jury.

Dated: July 29, 2009

Respectfully Submitted,

GILMAN AND PASTOR, LLP

/s/ David Pastor

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Tel: 201-567-7377 Fax: 201-567-7337

Attorneys for Plaintiff

#### CERTIFICATION OF PROPOSED LEAD PLAINTIFF PURSUANT TO THE FEDERAL SECURITIES LAWS

I, Jonathan D. Rahn, certify that:

engely in a perfect of general figure as with engineer.

- I have reviewed complaint and authorized its filing. 1.
- I did not purchase the security that is the subject of this action (Genzyme 2. Corporation) ("GENZ")) at the direction of plaintiff's counsel, or in order to participate in any private action arising under this title.
- I am willing to serve as a representative party on behalf of a class and will testify at deposition and trial, if necessary.
- My transactions in the security that is the subject of this litigation during the class period set forth in the complaint are as follows:

#### **Purchases:**

Date	Shares Bought	Price Per Share		
9/10/08	117	<b>\$79</b>		
9/12/08	57	\$80		
10/15/08	52	<b>\$68</b> \$371, "D"- OR WARNE		
10/29/08	<i>7</i> 9	\$71		

Sales (if any):	<u>Date</u>	Shares Sold	Price Per Share
	4/27/09	111	\$54

- I have not served as or sought to serve as a representative party on behalf of a class under this title during the last three years.
- I will not accept any payment for serving as a representative party, except to 6. receive my pro rata share of any recovery or as ordered or approved by the court including the award to a representative of reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

The foregoing are, to the best of my knowledge and belief, true and correct Signed: The O. Role statements.